

**VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS
BOARD OF HEALTH PROFESSIONS**

Workplan for the Review of Medical Laboratory Scientists and Technician

Background & Authority

By virtue of its statutory authority in §54.1-2510 of the *Code of Virginia* to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board is reviewing the need for regulation of laboratory scientists and technicians pursuant to a request from Delegate John M. O'Bannon. Delegate O'Bannon proposed House Bill 601 during in the 2010 Session of the General Assembly (attached). The legislation was continued to the 2011.

To govern evaluative reviews, the Board has developed formal criteria and policies referenced in its publication, *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions, 1998*. Among other things, the criteria assess the degree of risk from unregulated practice, the costs and benefits of the various levels of regulation, and the advantages and disadvantages of the various alternatives to regulation that might protect the public. By adopting these criteria and application policies, the Board has endorsed a consistent standard by which to judge the need to regulate any health profession. The aim of this standard is to lead decision-makers to consider the least governmental restriction possible that is consistent with the public's protection. This standard is in keeping with regulatory principles established in Virginia law and is accepted in the national community of regulators.

Study Scope & Methodology. The general scope of this study will be to provide an evaluative review of the policy literature, pertinent state and federal laws, malpractice and disciplinary data, potential economic impact, and public comment concerning the regulation of medical laboratory scientists and medical laboratory technicians in Virginia. The aim is to better understand the scopes of practice of these practitioners and issues relating to the need for adequate safeguards for the public's protection.

The Committee will make recommendations to the full Board concerning the practitioner group(s) to be selected. With the approval of the full Board, the Committee will examine the competencies currently expected of the selected practitioner groups in other jurisdictions to the degree that they exist. The Committee will focus their efforts in determining the answers to the following key questions for each group:

- What is the potential risk for harm to the consumer?
- What specialized skills and training do practitioners possess?
- To what degree is independent judgment required in their practices?
- Is their scope of practice distinguishable from other regulated occupations or professions?
- What would be the economic impact to the public if this group were regulated?
- Are there alternatives other than state regulation of this occupation which would adequately protect the public?
- If the Committee determines that this occupation requires state regulation, what is the least restrictive level that is consistent with the protection of the public's health, safety and welfare?

To answer the key questions, the following steps are recommended:

1. Conduct a review of the general policy literature, if any, related to the regulation of the respective group.
2. Conduct a review of the current relevant states laws and regulations.
3. Review malpractice insurance coverage data (if it is found to exist) in conjunction with other data to address Criterion One - Risk of Harm to the Public.
4. Review available reimbursement data to develop an estimate of how regulating this group may affect costs to address Criterion Five – Economic Impact
5. Prepare an initial draft report to the Board for public comment.
6. Conduct a hearing on the issue of the state regulation of this occupation, including any public health and safety issues germane to current practices as well as the potential fiscal impact which may result from such regulation.
7. Review all public comment, apply the Board's criteria and policies, and consider recommendations for changes in Virginia statute.
8. Prepare a draft with recommendations to the full Board.
9. Review the report and recommendations by the Board, and publish a draft report for consideration by the Department Director and Secretary.
10. If required based on recommendations by the Department Director and Secretary, amend the report and prepare a final report for their approval.

TENTATIVE TIMETABLE

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| May 4, 2010 | - Review and Approval of the Workplan |
| Jul. 1, 2010 | - First Draft Report to the Regulatory Research Committee |
| Jul., 2010 (TBD) | - Public Hearing |

Mid-Jul. 2010 (TBD) - Second Report with Summary of Public Comment to the
Committee for Review and Consideration of Policy Options

Aug., 2010 (TBD) - Public Comment on Resulting Report and Recommendations

Sept., 2010 (TBD) - Regulatory Research Committee Meeting to Review Final
Report and Make Final Recommendations to the Full Board.
Full Board to Vote on Final Report and Recommendations

Oct., 2010 (TBD) - Final Report to the Department Director and Secretary of
Health and Human Resources

Nov. 2, 2010 - Final Report Due to Legislative Services

Resources Required. The resources for this review are included in the FY 2010-11 Budgets of the Board of Health Professions. It is estimated that the review will require the services of a consulting policy researcher and 1/10th of the time of the Executive Director and general support from the Senior Regulatory Analyst and Operations Manager. The total cost associated for this project, to include staff time, telephone charges, photocopying, office materials, and court reporter, is estimated to be \$8,500.

HOUSE BILL NO. 601

Offered January 13, 2010

Prefiled January 12, 2010

A BILL to amend the Code of Virginia by adding in Article 4 of Chapter 29 of Title 54.1 sections numbered 54.1-2957.14 and 54.1-2957.15, relating to registration of medical laboratory scientists and medical laboratory technicians.

Patron-- O'Bannon

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Article 4 of Chapter 29 of Title 54.1 sections numbered 54.1-2957.14 and 54.1-2957.15 as follows:

§ 54.1-2957.14. Medical laboratory scientist and medical laboratory technician; definitions.

"Medical laboratory scientist" means a person who meets the requirements for registration as a medical laboratory scientist with the Board, and who engages in the development, performance, interpretation, and evaluation of laboratory tests in such areas as hematology, clinical chemistry, immunohematology, microbiology, serology/immunology, coagulation, molecular, and other emerging diagnostics.

"Medical laboratory technician" means a person who meets the requirements for registration as a medical laboratory technician with the Board, and who performs laboratory tests in such areas as hematology, clinical chemistry, immunohematology, microbiology, serology/immunology, coagulation, molecular, and other emerging diagnostics.

§ 54.1-2957.15. Registration as medical laboratory scientist or medical laboratory technician.

A. It shall be unlawful for a person to practice or hold himself out as practicing as a medical laboratory scientist or medical laboratory technician, or to engage in activities defined as constituting the practice of a person required to be registered as a medical laboratory scientists or medical laboratory technician as provided in regulations adopted by the Board, unless he has registered with the Board.

B. Every applicant for registration as a medical laboratory scientist shall pay the required fee and shall submit written evidence that the applicant:

1. Has received a baccalaureate degree from a regionally accredited college or university;

2. Has satisfactorily completed a program of experience and training required by the American Society of Clinical Pathology Board of Certification, American Medical Technologists, or other nationally recognized certification agency; and

3. Has passed a certification examination administered by the American Society for Clinical Pathology Board of Registry, the American Medical Technologists, or other nationally recognized credentialing agency.

C. Every applicant for registration as a medical laboratory technician shall pay the required fee and shall submit written evidence that the applicant:

1. Has received an associates degree or higher from a regionally accredited college or university;

2. Has satisfactorily completed a program of experience and training required by the American Society of Clinical Pathology Board of Certification, American Medical Technologists, or other nationally recognized certification agency; and

3. Has passed a certification examination administered by the American Society for Clinical Pathology Board of Registry, the American Medical Technologists, or other nationally recognized credentialing agency.

D. The Board shall adopt regulations to implement the provisions of this section.

2. That the Board of Medicine shall waive requirements related to receipt of the required baccalaureate or associates degree, satisfactory completion of an approved program of experience and training, and successful completion of a certification examination for persons seeking registration as a medical laboratory scientist or medical laboratory technician for any person who (i) makes application for registration before July 1, 2011; (ii) otherwise complies with regulations of the Board relating to moral turpitude; and (iii) has at least three years documented work experience as a medical laboratory scientist or medical laboratory technician.